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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/416,902	MCCAFFERTY ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44,46-48 and 51-60* is/are pending in the application.

4a) Of the above claim(s) *53-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44,46-48,51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/971,857.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/31/00, 8/1/03, 1/8/80*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's election of group I, claims 44-52 in the reply filed on 3/15/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 53-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/15/04.

3. Claims 45, 49-50 have been canceled by the amendment filed on 3/15/04. Claims 44, 46-48, 51-60 are currently pending; claims 53-60 are withdrawn and claims 44, 46-48, 51-52 are currently being examined in this application.

Priority

4. This application is a divisional of 08/484,893, which is continuation of 07/971,857, which is a continuation of PCT/GB91/01134.

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 07/971,857, filed on 1/8/93.

Information Disclosure Statement

6. The Ids filed on 8/1/03, 11/8/00, and 1/31/00 have been fully considered and entered into the application.

Drawings

7. The drawings filed on 10/13/99 have been considered.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 44, 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,837,500 (Ladner et al) (filing date 9/2/1998).

The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise a binding domain of an immunoglobulin, with a desired epitope (target).

The limitation 'wherein the nucleic acid in the library is provided by in vitro mutagenesis of an existing antibody coding sequence or pre-existing phage antibodies' is considered as 'product-by-process' limitation.

Ladner et al disclose a method of obtaining a nucleic acid encoding a proteinaceous binding domain (refers to the member of specific binding pair of the instant claims) that binds a predetermined target (refers to the desired epitope of the instant claims) (i.e., see claim 1). Ladner further discloses that method comprises a) providing a variegated population of filamentous phage (refers to the instant claim library of filamentous bacteriophage), each phage

providing a nucleic acid construct coding for a chimeric potential binding protein, each construct comprising DNA encoding a mutant of antibody domain(i.e., see claims 1, 4) (refers to the instant claim binding domain of immunoglobulin); b) expressing the potential proteins and displaying said potential binding domains on the outer surface of said phage; c) contacting said phage with the predetermined target material such that potential binding domains and the target may interact; d) separating the phage displaying a potential binding domain; e) recovering the phage (refers to the instant claim method steps) (i.e., see claim 1), and amplifying said binding domain encoding nucleic acids in vivo or in vitro (refers to the instant claim 48). Ladner discloses that the binding domains are antibody domains (refers to 'the binding domain of immunoglobulin' of the instant claims), and further teach that the population of the filamentous phage is obtained by subcloning a mixture of DNA encoding a plurality of different chimeric proteins comprising different potential binding domains. Ladner discloses a method to produce the target binding protein variants (refers to the instant claim 47). Thus, the reference clearly anticipates the claimed invention.

10. Claims 44, 46-48, 51-52 are rejected under 35 U.S.C. 102(a or e) as being anticipated by US 2002/0150881 A1 (Ladner et al) (effective filing date 9/2/1988).

The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise a binding domain of an immunoglobulin, with a desired epitope (target).

The limitation 'wherein the nucleic acid in the library is provided by in vitro mutagenesis of an existing antibody coding sequence or pre-existing phage antibodies' is considered as 'product-by-process' limitation.

Ladner et al disclose a method of obtaining a nucleic acid encoding a proteinaceous binding domain (refers to the member of specific binding pair of the instant claims) that binds a predetermined target (refers to the desired epitope of the instant claims) (i.e., see claim 1). Ladner further discloses that method comprises a) providing a variegated population of filamentous phage (refers to the instant claim library of filamentous bacteriophage), each phage providing a nucleic acid construct coding for a chimeric potential binding protein; b) expressing the potential proteins and displaying said potential binding domains on the outer surface of said phage; c) contacting said phage with the predetermined target material such that potential binding domains and the target may interact; d) separating the phage displaying a potential binding domain; e) recovering the phage (refers to the instant claim method steps) (i.e., see claim 1), and amplifying said binding domain encoding nucleic acids in vivo or in vitro (refers to the instant claims 48, 52). Ladner discloses that the binding domains are antibody variable domains (refers to 'the binding domain of immunoglobulin' of the instant claims), and one more residues correspond to residues in the hypervariable region of said domains (i.e., see claims 4-5). Ladner et al teach that the population of the filamentous phage is obtained by subcloning a mixture of DNA encoding a plurality of different chimeric proteins comprising different potential binding domains. Ladner discloses a method to produce the target binding protein variants (refers to the instant claims 47, 51 method)(i.e., see claim 10). The 'antibody variable domains' of the reference claims read on the instant claim 'single chain antibodies or scFV,' because the

reference teaches that 'the single chain antibody is a single chain polypeptide comprising two antigen binding regions to fold together to bind an antigen, ...and the two antigen binding regions must be variable domains of known antibody.' Thus, the reference claim variable domains of an antibody read on the scFv of the instant claims. Thus, the reference clearly anticipates the claimed invention.

11. Claims 44, 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,427,908 (Dower et al) (filing date 5/1/1990).

The instant claims briefly recite a method of obtaining a member of specific binding pair, by contacting a library of filamentous bacteriophage particles displaying a population of specific binding pair members, which comprise a binding domain of an immunoglobulin, with a desired epitope (target).

The limitation 'wherein the nucleic acid in the library is provided by in vitro mutagenesis of an existing antibody codign sequence or pre-existing phage antibodies' is considered as 'product-by-process' limitation.

Dower et al teach filamentous bacteriophage library encoding antibody fragments (refers to the instant claim binding domains of immunoglobulin). The reference teaches that the bacteriophage library is screened for antibody fragments which bind specifically to a ligand of interest (refers to the desired epitope of the instant claims). The reference teaches that the bacteriophage particle encoding the antibody fragment that binds specifically to the antigen is selected (i.e., see claim 1), and the bacteriophage particles are enriched by repeating the selection step. Dower et al teach that the nucleic acid encoding the antibody fragment is isolated (refers to the instant claim 48) (i.e., see claim 8). The reference further teaches that the library is

constructed by cloning the cDNA from the donor cells (i.e., see column 8). The reference further teaches that the phage particles displaying the specific antibody fragment are propagated, and the phage is harvested and DNA prepared and sequences to determine the DNA and amino acid sequence (refers to the instant claims 47-48) (i.e., see column 12). Thus, the reference clearly anticipates the claimed invention.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 44, 46-48 and 51-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of U.S. Patent No. 5,969,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claimed method recites 'a method of producing a member of specific binding pair, whereas the instant claim recites method of obtaining a member of a specific binding pair member. Both the reference method and the instant claim method result in specific binding pair member. And further the reference claims do not specifically teach 'scFv', however the 'single polypeptide chain comprising the binding domain of an antibody' would read on the scFv. The reference claim 7 recites that eh library is obtained from in vitro

mutagenesis of nucleic acid encoding the immunoglobulin. The reference claim 19 recites that the nucleic acid derived from the selected phage is used to express said specific binding pair member (refers to the instant claims 47-48, 51-52). The reference claim 23 relates to the instant claims 47 and 51; and the reference claim 24 relates to the instant claims 48, 52.

14. Claims 44, 46-48, 51-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/803,653. Although the conflicting claims are not identical, they are not patentably distinct from each other because The reference claim method does not specifically recite that the specific binding pair member comprises a binding domain of immunoglobulin or svFv, however the binding molecule of the reference reads on the scFv and immunoglobulin domain of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 44, 46-48, 51-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/803,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claim method does not specifically recite that the specific binding pair member comprises a binding domain of immunoglobulin or svFv, however the binding molecule of the reference reads consists of dAb, which reads on the scFv and immunoglobulin domain of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

22 July 2005

PADMASHRI PONNALURI
PRIMARY EXAMINER